METHOD AND APPARATUS FOR MONITORING INTRA OCULAR AND INTRA CRANIAL PRESSURE

DESCRIPTION

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention generally relates to non-invasive techniques for diagnosis of medical conditions, and in particular to use of such techniques for monitoring pressure within the cranium.

Background Description

Pressure increase in the brain, which is contained within the skull, is a serious medical condition that can be life threatening. The brain is surrounded by cerebrospinal fluid; the pressure of the fluid, known as intra cranial pressure (ICP), is carefully controlled by homeostatic mechanisms in the body. In pathological circumstances such as stroke or head injury, elevated ICP poses a clinical problem that must be carefully managed to prevent severe brain damage or even the death of the patient. Intra cranial pressure changes can be detected non invasively using acoustic stimulation and analysis. The brain and the skull are coupled resonant systems that will respond in a predictable fashion to pressure

2

increases given the bio-boundary conditions.
Changes in acoustic damping are correlated with
changes in cerebral spinal fluid (CSF) or intra
cranial pressure (ICP). Intra cranial pressure is
currently monitored invasively, with monitoring
devices implanted within the skull cavity or lumbar
punctures.

There are two "windows" to the interior of the
skull for "seeing" brain pressure: the ear and the
eye. Intra cranial pressure (ICP) in the brain is
DIRECTLY communicated to both the eye and ear. The
eye is more convenient to non invasively monitor
changes in ICP. Ear monitoring of changes in
cerebral spinal fluid (CSF) pressure have been
attempted but have not resulted in a feasible
clinical device. Direct measures of skull
vibration by using ultrasonic probes have also been
attempted, but with limited success because it is
technically complicated, and is not a promising
clinical alternative. Eye pressure does correlate
with CSF and various approaches have been used
since eye pressure assessment is a common
ophthalmological procedure.

Two types of intra ocular pressure measurement
have been reported, with varying correlations to
intra cranial pressure (ICP). These include non-
contact air tonometry, which measures intra ocular
pressure. This technique has produced conflicting
results and at best provides only a rough estimate
of ICP. The other reported technique is
ophthalmodynometry, which is an aplanatic
technique. This technique applies pressure to the
cornea and measures the intra ocular arterial pulse

wave. Pressure is applied to the corneal surface until the intra ocular arterial pulse wave (produced by the ophthalmic artery) is obliterated. The pressure at which this happens has been termed intra cranial arterial pressure and some have used this pressure to infer changes in ICP. However, this measure cannot be equated with ICP.

There have been previous attempts by other researchers to acoustically measure ICP in animals, but although they have proven the validity of the concept, they have not been practical for portable use in humans. Semmlow and Fisher ("A noninvasive approach to Intra cranial pressure monitoring", *Journal of Clinical Engineering*, 1982, vol. 7, pp. 73-78) observed in young dogs that the response of the head to low-level audible vibrations correlates with ICP elevation. Stevanovic et al. ("The effect of elevated Intra cranial pressure on the vibrational response of the bovine head", *Annals of Biomedical Engineering*, 1995, vol. 23, pp. 720-727) demonstrated the correlation of audible vibration with ICP in sheep, artificially elevating ICP and monitoring the acoustic signal. However, although their method did not require surgery within the skull cavity, it did require implantation of screws in the skull, making it impractical for a portable system.

There is a need for a technique that can be used to non-invasively monitor intra cranial pressure (ICP). There is a need for a portable, non-invasive sensor for measuring ICP in casualties with traumatic head injury, suitable for use in the battle area and during medical evacuation as well

as in hospital conditions. This will allow
monitoring to prevent secondary brain damage.
Timely identification and treatment of elevated ICP
will greatly improve the chances of survival of
these patients.

SUMMARY OF THE INVENTION

It is therefore an object of the present
invention to provide a non-invasive technique for
detecting increases in brain pressure.

Another object of the invention is to provide
a portable sensor for measuring ICP suitable for
use at trauma sites as well as in hospital
conditions.

A further object of the invention is to enable
timely identification and treatment of elevated
ICP.

The technique of the invention is to use
acoustic signals and transducers on the surface of
the skin of the head and over closed eyelids to
non-invasively monitor intra cranial pressure.
Intra cranial pressure changes are detected non-
invasively using acoustic eye patches that are
comfortable, accurate and provide a rapid and
sensitive reading. A piezoelectric film sensor is
placed in contact the eye or eyelid of each eye.

An method and apparatus according to the
invention measures intra cranial pressure uses an
acoustic eye patch conformably adapted to an
eyeball of a patient, the eye patch having sensors
for measuring acoustic signals. The eye patches
have piezoelectric film sensors for measuring the

acoustic signal. An ultrasonic sweep generator applies acoustic signals across the skull of the patient, the signals sweeping a predetermined range. An analyzer determines from an output of the acoustic eye patch an intra cranial pressure. In one embodiment the predetermined range is in the ultrasonic band and an analyzer determines from the output of the sensors a resonant frequency and a damping of acoustic amplitude at said resonant frequency, there being a correlation between said damping and intra cranial pressure. In another embodiment the predetermined range includes a range less than 20 kHz and the analyzer determines retinal artery pulsations, with pressure being applied to the eye until the pulsations disappear, such pressure being a measure of intra cranial pressure.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other objects, aspects and advantages will be better understood from the following detailed description of a preferred embodiment of the invention with reference to the drawings, in which:

Figure 1 is a conceptual schematic showing the effects of intra cranial pressure.

Figure 2 is a diagram showing a piezoelectric film sensor in contact with the eye or eyelid.

Figure 3 is a diagram of an apparatus for acoustic stimulation of the brain.

Figure 4 is a graph showing the intensity of vibration across a range of frequencies recorded at

the eye responsive to sound energy applied to the skull.

Figure 5 is a table of invasive measurements of ICP for five patients used for calibrating acoustical recordings made from the skull and eye.

Figure 6 is a graph showing acoustic intensity over a frequency range recorded at the eye for two patients with different ICP values.

Figure 7 is a graph showing the consistency of separate acoustic intensity recordings for the same patient.

Figure 8 compares graphs showing a linear relationship between ICP and damping of acoustic intensity at a resonance frequency in humans and dogs.

Figure 9 is a graph showing a linear relationship between ICP and damping of acoustic intensity at several frequencies in the resonance range.

Figure 10 is a table showing differences in direct ICP measurements and acoustic intensity attenuation recorded at the eye for various patient pairs.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT OF THE INVENTION

Referring now to the drawings, and more particularly to Figure 1, there is shown a conceptual schematic of a skull 110, within which and upon which the brain's cerebral spinal fluid (CSF) exerts pressure 120. This pressure 120 is not only communicated to the skull 110 but is also

communicated to the eye 130 and the ear 140. The brain and the skull are coupled resonant systems that will respond in a predictable fashion to pressure increases. Changes in acoustic damping are correlated with changes in cerebral spinal fluid (CSF) or intra cranial pressure (ICP).

Any physical or biological system that has an acoustic resonance will be characterize by a narrow range of frequencies which will cause the system to oscillate, i.e. force resonance. A fine wine glass can be forced into vibration and it will oscillate with the greatest amplitude at its resonance frequency. Sometime the amplitude is so great the glass shatters. However, natural resonance can be reduced in amplitude by damping. If the glass is filled with wine or a gel the amplitude of oscillation will be reduced. Furthermore, if the wine or gel is placed under pressure, further amplitude reduction will be observed.

The skull, brain and eye are all resonant structures. The skull's natural resonance is around 2 kHz. That is, if acoustic energy with a frequency of 2 kHz is applied across the skull, the intensity of the acoustic energy measured elsewhere on the skull will be high relative to such measurements taken at frequencies which are outside the range of natural resonance. With increased ICP there will be more pressure on the inside of the skull such that its natural resonant oscillations will be damped. The resonance of the brain is about 15 kHz and with increased ICP its oscillation too will be damped.

8

The brain's damped oscillation in response to
forced vibration (e.g. sound applied to the head)
will be communicated to the eyeball and can be
recorded off the lid. Thus increased ICP increases
damping of acoustic vibrations in the brain and
skull, which will reduce the acoustic oscillation
of these structures, and that reduced oscillation
can be recorded on the eye. The amount of
oscillation reduction is directly proportional to
actual ICP.

Other frequencies than the resonant frequency
can be used, but the effects of increased ICP will
be more difficult to measure because at non-
resonant frequencies the difference between natural
oscillation and oscillation under damping will be
very small, due to the frequency response of any
resonant structure. The largest difference between
the natural and damped frequencies is near the
resonant frequency. However, the method of the
invention does not use a specific frequency because
there will be range of resonant frequencies in the
human population due to individual geometries.

Turning now to Figure 2, there is shown a
diagram of the eye resonance pressure effect used
by the present invention. The invention
capitalizes on the acoustic resonant properties of
the eye 210, a globe that can be modeled accurately
as a sphere. Sixty percent of the globe is bounded
by bone, representing a high impedance interface.
Calculations of resonant frequencies range from
approximately 30-50 kHz (e.g. a nominal calculation
of 33-43 kHz, as shown). Ultrasonic resonance is
expected, given the small radius of the eye (~0.75

cm). However, variations in anatomical features and departures from precisely spherical geometry make exact predictions difficult. Therefore, the method of the invention is to sweep tones from well below to well above projected resonant frequency. This is a prudent tactic to ensure that resonant frequencies will be covered.

As pressure is increased by the CSF of the brain on the globe of the eye 210, intra ocular pressure (IOP) rises. Increases in IOP will increase the acoustic damping. Increased acoustic damping will be reflected in a reduction in intensity of the signal communicated within the eye and to that portion 220 of the eye closest to the sensor 230 placed comfortably over the closed eyelid or the eye. The sensors 230 are constructed of piezoelectric film, coated with Mylar, and record the intensity of the signal damped by increases in IOP.

The eye pressure is an indicator of brain ICP. The pressure increase in the brain can be detected as a change in the sound propagation amplitude through the eye. Conversely increased eye pressure, in the context of normal brain ICP, will also be detected as a change in acoustic propagation through the eye. As the ICP or cerebral spinal fluid pressure (CSF) increases there is increased acoustic damping in the eye which will be reflected as a change in acoustic pressure. The sound waves are picked up by a piezoelectric film sensor placed in contact with the eye or eyelid. Furthermore, if the sensor is placed in the eye, a high frequency response can be

10

consistently recorded. However, if the recording
sensor touches the skull, the resulting spectrum
looks much like that recorded from the skull.
Consequently, it is important that the sensor not
come into contact with the eye socket.

Figure 3 shows a monitoring apparatus for
stimulating the brain with acoustic vibrations and
recording from the eye or eyes and/or the skin of
the head the resulting acoustic energy. The
preferred location for a recording sensor for the
head is over the forehead. Noise output 350 is fed
to amplifier 340 and the amplified signals are
applied to the brain via drivers 310 mounted on a
headband, generally in front 310 and in back (not
shown). The signals pass through the brain and are
recorded at eye sensor 320 and/or a forehead sensor
315, the recordings then providing signal input 360
to signal analyzer 330.

Figure 4 shows a spectrum of vibration
recorded from a closed eyelid in response to sound
energy delivered to the skull. The acoustic energy
was applied in a scan covering the range up to 50
kHz. The corresponding readings at the eye were
attenuated in the range of -5 to -10 db. Modeling
the eye as a sphere under some boundary condition
would predict a resonance in the 30-50 kHz range.
Actual recordings as shown in Figure 4 indicate a
range of 33-45 kHz for resonance. Clearly, the
globe of the eye is not an exact sphere. The upper
tracing 410 is under normal pressure and the lower
tracing 420 is recorded during a valsalva maneuver,
which elevated the ICP and dampened the recorded
signal.

11

Figure 5 is a table showing ICP measurements for five subjects who were implanted with a pressure sensor in the skull. The subjects are identified by their initials in the patient column 510. For each of these subjects, the invasive monitoring method (ventriculostomy) is shown in column 520. The measured ICP is shown in column 530. These measurements served as reference for the acoustical recordings made from the skull and eye. The ICP pressures ranged from 7-20 mm Hg. Pressures under 5 Hg are considered normal. Pressures over 10 mmHg are considered elevated and warranting clinical management.

It can be seen from Figure 5 how calibration of the acoustic measurement is accomplished by reference to patient data where ICP is measured with a sensor placed directly in the brain (i.e. ventriculostomy as recorded in Figure 5), and at the same time acoustic signals are measured at the eye as described above.

Figure 6 shows eye sensor recordings of relative acoustic intensity from two individuals, one 610 with normal ICP (2 Hg) and one 620 with slightly elevated ICP (12 Hg). Note the reduction in acoustic amplitude (i.e. further attenuation) with elevated ICP.

Figure 7 demonstrates the repeatability of the measurements taken using the technique of the invention. Measurements of the relative intensity of acoustic signals over a frequency range up to 50 kHz received at an eye sensor were taken from the same subject on two separate occasions. Trace 710 shows the results on one occasion and trace 720

12

shows the results on a second occasion. It will be
observed that the two traces provide results that
are very close, making it difficult to distinguish
the traces shown on Figure 7.

The left panel 810 of Figure 8 shows that
there is a linear relationship between ICP (the
logarithmic horizontal scale, in ICP delta over
normal, i.e. the difference between the measured
ICP and a normal ICP) and eye recordings of sound
amplitude (relative attenuation, in db volts, on
the vertical scale) in human subjects. In this
particular example 36 kHz was chosen as the
resonant frequency because it had the best signal
to noise ratio in the recording, and data for five
human subjects is shown. A linear relation between
ICP pressure and skull vibration is also suggested
in the dog model shown in the right panel 820,
using data taken from Semmlow and Fisher. While
Semmlow and Fisher used skull sensors and did not
use, or indicate an understanding of the
significance of, resonant frequencies the linear
relationship between increased cranial pressure and
damping of acoustic signals is nonetheless
demonstrated. Increased sound attenuation was
arbitrarily defined as damping. Damping reduces
sound transmission as indicated in the eye
recordings in humans as well.

Figure 9 shows that other frequencies (in the
resonance range) can also be used to predict ICP
based on a linear function. As with the first
panel 810 of Figure 8, the ICP delta over normal is
shown logarithmically along the horizontal scale
and relative attenuation of the acoustic signal is

shown on the vertical scale. Data is plotted for
frequencies of 36 kHz (whose results are summarized
by plot line 910), 38 kHz (whose results are
summarized by plot line 920) and 40 kHz (whose
results are summarized by plot line 930). Likely
frequencies higher or lower than this range can
also be used. It should be noted that the
differences in degree of resonance within the
resonant frequency range are not in the form of a
smooth bell curve. This may be seen from the shape
of the graph within the predicted range shown on
Figure 4. Thus the linearity comparisons shown in
Figure 9 between data for 36 kHz, 38 kHz and 40 kHz
(as shown by comparing lines 910, 920 and 930,
respectively) may not be in the same order as the
resonant frequencies themselves.

The baseline 940 in Figure 9 represents a
nominal value that serves as a practical dividing
line between cases needing clinical attention and
those where clinical attention may not be called
for. In practical operation, the invention will be
used by medical personnel at a trauma site. The
analyzer of the invention may be implemented by an
algorithm that automatically identifies a resonant
frequency from an acoustical scan and uses
calibration data (as described in connection with
Figure 5) to correlate signal damping at the
resonant frequency with an equivalent ICP. The
algorithm then provides at several levels the
results of the acoustic readings translated into an
equivalent cranial pressure. Below a certain level
(e.g. 2 mm Hg), the readout of the analyzer would
simply indicate that cranial pressure is not a

14

concern. Above that level but below a baseline
level, the readout would indicate that the
patient's cranial pressure condition is not clear,
but is not necessarily of concern. A medical
technician using the invention may or may not
continue to monitor the patient.

However, above the baseline, the readout of
the analyzer would show the numerical value of the
equivalent cranial pressure. The clinical concern
is whether the pressure is increasing. After a
delay, the length of which would be based upon the
experience and judgment of the medical technician
using the invention, another reading would be
taken. If the reading showed an increase in intra
cranial pressure, medical attention would be
indicated. In general, variability between human
subjects and variability in the circumstances make
it difficult to say whether a particular ICP
reading is elevated or not. The research
underlying the invention and disclosed herein
shows, however, that there is enough commonality
across a range of human subjects and enough
repeatability in the invention's measures of ICP
that the invention can be of practical utility in a
clinical setting.

Figure 10 shows differences in direct ICP
measurements and intensity attenuation recorded on
the eye as seen for various combinations of
patients over the range of 7-20 Hg in five
subjects, the same five subjects shown in Figure 5
and used in Figure 9. These acoustical difference
data were significant at the $p = 0.0001$ level. The
data in Figure 10 demonstrates that the correlation

between ICP and the measurement of acoustic attenuation in accordance with the invention is useful across a range of human subjects. Even when the results from different subjects are compared (here shown by measured ICP), the comparative measures of acoustic attenuation (here shown in a delta of dB volts) are consistent.

It should be noted that there are low frequency oscillations of the eye that are a reflection of cardiovascular support. If the eye sensor 240 is placed on the eye these low frequency oscillations (<20 Hz) can be recorded. If pressure is placed on the globe 210 (e.g. by simply pressing the sensor patch in toward the eye) there will be a point that the globe pressure is equal to the ICP. This can be detected by the eye sensors. Thus the method of the invention can be used to detect retinal artery pulsations using the piezoelectric film sensor 230 on the eye, and then to determine ICP by applying pressure on the eye until pulsations disappear.

Additional value using this technique to measure ICP may lie in its use in conjunction with trans-cranial acoustical measurement. In this manner, changes in an acoustical signal generated at the eye may be measured trans-cranially, or trans-cranially produced acoustical signals could be measured at the eye as described above. Thus as ICP changes the acoustical signals generated across these points will be changed. Furthermore, the ability to bilaterally measure the signals using both eyes may assist in confirming measures. Alternatively, the potential may exist to allow

detection of hemispheric location of large
accumulations of intra-cranial blood after trauma,
such as epidural and subdural hematomas.

A non-invasive monitor is an important advance
in emergency room medicine, for immediate use
before implantation of invasive sensors. The
present invention is a notable improvement over the
few previous acoustic devices for assessing intra
cranial pressure because it is simple, does not
require extensive computing power, and is reliable
from trial to trial. If the brain is stimulated at
or near its resonant frequency the amplitude
recorded from external sensors will reflect damping
produced by increases in pressure. The acoustic
features of fluid pressure increases are stable.

While the invention has been described in
terms of preferred embodiments, those skilled in
the art will recognize that the invention can be
practiced with modification within the spirit and
scope of the appended claims.